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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,131	02/13/2002	Babu J. Mavunkel	219002028310	9859

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,131

Applicant(s)

MAVUNKEL ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 39-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 39-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Jan. 26, 2005 have been entered and considered carefully.

Claims 39-78 are pending.

2. The rejection of claims 39, 40, 42, 45-46, 49, 60, 63, 68-71 under 35 USC 112 second paragraph is maintained for reason of record.

The argument presented by attorney is that the terms are definite and understood since they flow logically for the phrases in referring to those substituents. This is not persuasive. Please note that in so far as the compound claims are concerned, the terms defining chemical structure must provide specific and particular "structural" arrangement of the molecules. Applicants attention is drawn to the term "including one or more heteroatoms" such as an alkyl group, is the structure $\text{CH}_2(\text{OCH}_3)\text{CH}_3$ which chemically is alkoxy substituted alkyl ? or is it $\text{CH}_2\text{-OCH}_2\text{-OCH}_3$ which chemically is alkoxy-alkoxy-alkyl ? or is it -CH-CH=O which chemically is an lactone ? or is it CH-pyridyl which chemically is pyridylmethyl? Please note for each of the exemplified moiety, no antecedent basis or description or enablement was found in the specification yet all of these can be embraced by the term heteroatom included alkyl.

The argument with respect to proinflammatory response is not reach through is not persuasive. Initially, applicant's attention is drawn to that the definition of "reach through" is not what applicants interpreted it to be but must be complied with the trilateral definition for which a copy is attached for applicants' convenience. The mere fact that the filed of "proinflammatory response" associated with cytokine is a continuous and new "scope" is being continuously added to the filed, is evidence that such term is "reach through" since the term is reaching to all new development of the citation i.e. see CA 138-142 the continuous addition of new IL receptors.

Besides, treating inflammation and treating "inflammatory response" is not analogy since treating inflammatory response is actually treating "deficiency" of an inflammation which should occur (see Cecil Textbook of medicine). Therefore, the term treating "proinflammatory

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response” can not be ascertained, especially when such term is continuously being developed by the field (see CA references).

3. The rejection of claims 39, 40, 42, 45-46, 49, 60 and 75-78 under 35 USC 112 first paragraph is maintained for reason of record.

The argument that the specification described multiple IL receptor and the Markush scope requires no more than routine experimentation to achieve the claimed scope is not persuasive especially in view of the references recited supra from the field. The recitation of IL1, IL6 and IL8 as argued by attorney provided clear evidence that although the term “proinflammatory response” is reaching through all the newly discovered IL in the recited CA references (see section 2), neither antecedent basis nor enablement for such “claimed” scope can be supported from the specification.

In addition with the diversity and unpredictability of the cytokine function being not well defined in the field (see references supra and of record), attorney’s mere argument without factual evidence can not support the allegation that the enormous Markush compounds for which a definitive scope can not be ascertained (see rejection supra) requires no more than routine experimentation to achieve the scope of the method claims.

4. The rejections of claims 39, 40, 42, 45-46, 49 and 60 under 35 USC 102(a) of CA 131:97650 or alternatively under 35 USC 103(a) over CA 135:313624 are maintained for reason of record.

Applicants made no rebuttal to the rejections.

5. The rejection of claims 39-78 under the judicially created doctrine of obviousness type double patenting is maintained. Applicants made no rebuttal or filed acceptable terminal disclaimer.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7: Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 16, 2005


Celia Chang
Primary Examiner
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